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Re: Dawn Kennedy v. City of Philadelphia d/b/a Philadelphia Police Department
Expert Report
Report delivered via EMAIL: dberlin@weisberglawoffices.com

Dear Mr. Berlin:

I have reviewed the documents relevant to the above referenced case. However, before delving into the specifics of this case, I should provide a summary of my background in drug testing with an emphasis on the hair testing aspects.

My Educational Background and Experience

I have a Bachelor of Science Degree in Chemistry, *Magna cum Laude*, from the University of North Carolina in Chemistry (1977), a Doctor of Science degree from the Massachusetts Institute of Technology in Organic Chemistry (1982), and a National Research Council Post-Doctoral Associateship at the Naval Research Laboratory (1982-1984). I have been a member of the American Chemical Society since 1977, the American Association for the Advancement of Science since 1983, and a previous member of the Society of Hair Testing. I have been certified as an expert witness in Federal District Court, State Courts, Military Courts Martial, and several Military Administrative Board Hearings.

I have been employed at the Naval Research Laboratory (NRL) as a Research Scientist since 1984 and with my specialties and research are quite broad.[1] Since that time, I have employed various forms of mass spectrometry to detect trace analysis in complex matrices, designed, built, and repaired scientific instrumentation, designed sensors and sensor systems for various environmental compounds, developed novel immunoassays and DNA assays, and developed electronic packages and software control programs. I have been commended for some of my work with the awarding of two Edison Patent Awards and two Allen Berman Publication Awards.[2] I have received additional recognition outside of NRL from NASA (2002), from the Federal Laboratory Consortium

for Technology Transfer (2001), and the Midwestern Association of Forensic Scientists and Southern Association of Forensic Scientists, Paducah KY, (Paper Award Winner, 1995).

This expert report is divided into several sections:[3]

- A brief history of my involvement with hair testing
- The problems of passive exposure with hair testing
- The issue to bias in hair testing
- The lack of definitive markers of drug use, and the lack of scientific consensus on what a positive sample means
- The deficiencies in Officer Kennedy's hair sample analysis by Omega Laboratories, Inc.
- Inconsistences with other analysis
- Alternative means of drug testing
- Conclusions

A Brief History of my involvement with hair testing

In the mid-1980s, the Bureau of Naval Personnel (BUPERS) was approached by Werner Baumgartner about a novel way to screen individuals for drug use, *i.e.* hair analysis. At that time, the Navy was one of the largest (if not the largest) users of urine testing in the world and was always open to new ways to conduct its testing. BUPERS tasked the NRL to oversee and to fund a preliminary study, using personnel in drug rehabilitation at a Navy facility, to evaluate hair testing for cocaine and THC detection. This initial study showed some promise. Because the Navy required two independent confirmations of the presence of drugs before a positive sample could be reported and with only RIA being employed at that time, I was tasked by BUPERS to develop a confirmation test using mass spectrometry. I presented the results of my research at the American Society for Mass Spectrometry Conference in 1988 and one of the first international hair testing meetings at the National Institutes of Standards and Technology (NIST). During the NIST meeting, I proposed that the then current concept of hair trapping drugs in inaccessible regions only from the blood was incorrect. Instead, I proposed what is now, widely accepted by the scientific community, of multiple sources for drugs appearing in hair. I also discussed the following four concepts:

- Hair traps drugs from internal and external sources - sweat and sebum being one source of the external contamination.
- The external sources of drugs confound the data interpretation between user of drugs and mere exposure.[4]
- Different hair types have differencing susceptibility to internal uptake and external contamination and therefore a "hair type bias" is likely.
- Detection of low use is difficult and unproven.

In the intervening 30+ years, I have conducted a number of research programs on these four issues. I have published 24 papers in the peer-reviewed literature on drug testing, several book chapters, and have authored or co-authored over 40 presentations at scientific meetings and technical working groups. The Navy has been conducting urine

testing for over 40 years and currently tests approximetly one million urine samples/year for seven+ drugs of abuse. The Navy has not replaced their urinalysis program with hair testing and I believe this is because of the problems that I had uncovered in my research. I note that even today the Philadelphia Police Department uses urine testing as their main drug deterrent.[5]

Passive exposure in hair testing

Although less is known about marijuana, considerable evidence shows that other drugs and compounds can be incorporated into hair and not be easily removed. One may ask, "Can external contamination occur in real-life?" Basically yes. We conducted a study on the children of cocaine-addicted mothers.[6] Because these were young children (1-13 years of age), knowing use of cocaine was unlikely. The pattern of cocaine concentration in the hair of the children varied widely by household. However, on aggregate, their levels mirrored the cocaine using mothers such that no cut-off would separate the two populations. This study was criticized because we had minor differences between our decontamination procedure and commercial decontamination procedures. To partially resolve this issue, we sent some of the hair samples to a commercial laboratory. Their results were similar to ours.[7] An additional critique is that the children may be microingesting cocaine. However, one subject, a one-year old child, had 1003 ng/10 mg of cocaine in his/her hair. Even taking into consideration differences in body weight, it is not clear that this child could have ingested that much cocaine.[8] Furthermore, when the hair sample was taken, a urine sample was also obtained. No cocaine metabolite was found. Thus, the macroingestion[9] would have had to stop several days before the hair sample was obtained, which is unlikely. This is not the only study on the children of drug using parents. A major, commercial, hair-testing laboratory employs hair testing of children for several social service organizations.[10] Positive hair findings, of which there are many, are part of the evidence for removing children from a drug-using environment. Since our pioneering work, there have been over a dozen published scientific studies examining children living in contaminated environments. Mostly, their conclusions are similar to ours – children pick-up contamination from their environment and incorporate it into their hair.

Finally, one may ask are there any *in vivo* studies where drug-negative adults have been exposed to drugs and have hair positive results? Again, the answer is yes. Romano, *et al.*, exposed four individuals to cocaine by placing cocaine on their hands and having them rub their hair.[11] Hair was taken periodically after the contamination. The authors tried to extensively decontaminate the hair but could not. Every sample was positive and the hair was still positive three months later. More importantly, the "metabolite" benzoylecgonine started to form in the hair, *in vitro* and reached a level of approximately 30% of the cocaine level in the hair by the end of the study. An additional study was done with heroin with similar results – external application of drugs mimics drug use.[12]

In summary, there are a large number of studies that have exposed hair to drugs and have been unable to completely decontaminate the hair. Examining children, living in

an environment where drugs are used or had been used, indicates that passive exposure on the surface of the hair can occur and generate false hair tests under real-life scenarios. Examining adults, who have been intentionally contaminated, also shows that contamination is difficult to remove. This body of literature indicates that hair testing, more likely than not, measures exposure to drugs rather than only use.

How drugs get incorporated into hair and implications on bias in hair testing

Hair is a complex organ. It is composed of a number of sub-structures, but for the purposes of this discussion, I will only consider two: (1) The cortex or the inner part of the hair, thought to be the repository of the absorbed drugs, and (2) The cuticle, or the outer part of the hair, which protects the inner part from external contamination. A micrograph of intact human hair is shown in Figure 1a. The scale-like entities are the cuticle. In aqueous environments, the cuticle opens-up and allows molecules to penetrate into the cortex.[13] Furthermore, the liquid, which swells the cuticle, provides a vehicle for the rapid transport of materials. When the liquid is removed, the cuticle closes and helps entrap the drugs. Therefore, contamination applied to hair in the dry state is easily removed, whereas contamination applied in solution is not.

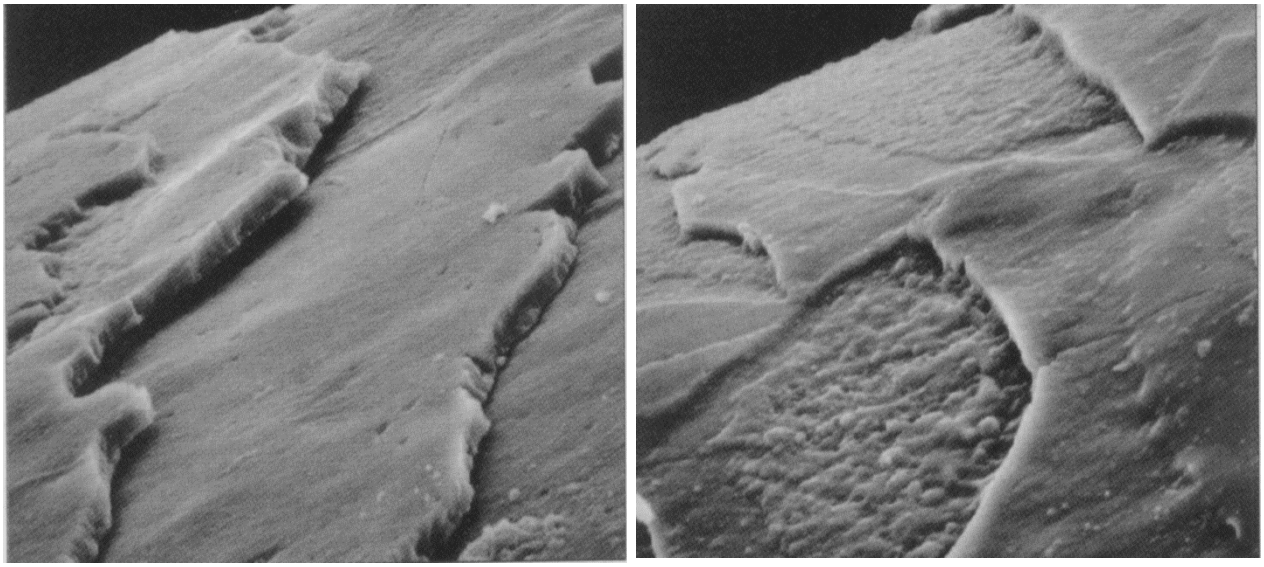


Figure 1 – Structure of human hair cuticle.[14] Micrograph (A - left) is normal human hair. Micrograph (B - right) is hair that has a damaged cuticle due to cosmetic treatment.

Drugs are incorporated into hair via diffusion where they then bind to internal structures. Diffusion into hair depends on a number of factors, time, vehicle, and concentration being the major ones. For the amine containing drugs (cocaine, amphetamines, opiates, PCP, etc.), once they diffuse into the hair, it is thought that they bind to melanin or protein associated with melanin and then become difficult to remove. Thus, one could hypothesize that as individuals of color having more melanin in their hair, then also will bind higher concentrations of drugs.[15,16,17]

Almost nothing is known about the binding of THC and THC-COOH to melanin. To my knowledge, only one study using the fur of rats has been reported in the literature as an abstract of the summary of her Ph.D. thesis work.[18,19] However, although THC and THC-COOH are not considered to bind to melanin (as it has not been well studied), they are suspected to bind to sebaceous secretions. Oil can play a role in bias.

I will not amplify on studies examining drug users and purporting to show no bias because this is the wrong issue. Bias in individuals who ingest drugs, although I believe it is real, is not the issue in this case.[20] Here it is bias in individuals who have been exposed to drugs. Well-controlled, laboratory studies where hair samples are exposed to drugs are more relevant. Little is known about exposing hair to THC or THC-COOH. However, the aspects of diffusion known from other drug classes are insightful. Figure 2 shows the exposure negative hair of different types to trace levels of cocaine.

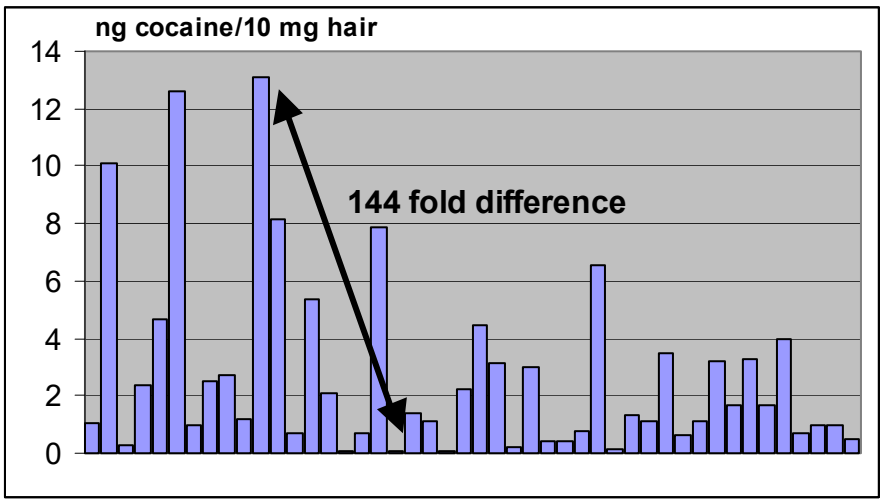


Figure 2 – Incorporation of cocaine into different hair types. Data from[21]

There is not a good correlation of uptake of cocaine to hair color. If not hair color, then what could account for this approximately 144 fold difference in incorporation rates in these 45 different hair "types"?[22] We have postulated several factors: genetics, hair color, and cosmetic treatment (among others) to account for different incorporation rates.[23] Because hair color plays only a small role, we have termed this bias "cultural bias" with the implication that cosmetic treatment is the dominant factor.

To cause a hair positive, there first must be the opportunity for drugs being present. Then the drugs must penetrate the cuticle and enter the cortex, which contains the melanin granules. Although melanin and therefore hair color plays a role in the final amount of binding (if equilibrium is reached), the first step is getting past the cuticle. As mentioned above, water (or sweat) is important in swelling the cuticle. Additionally, prior cosmetic treatment is also important because it damages the cuticle (see Figure 1b) and reduces the requirement for water. Furthermore, some of the cosmetic treatments placed on cosmetically straightened hair to add shine and prevent breaking can enhance transfer and binding of drugs. Most often these treatments contain oil and glycerol. Glycerol serves are a replacement for water and is known to aid in drug transfer from keratin to an inert object.[24] Furthermore, the oil absorbs drugs from the

environment and preconcentrates them on the hair. Thus, anyone applying such materials to their hair have a ready system for hair contamination: the oil absorbs and concentrates drugs from the environment, the glycerol swells the hair and provides a vehicle for drug transfer, the conditioning treatment is not replaced frequently providing lengthy exposure times (normally 48-72 hours), the damaged hair is less resistant to drug transfer, and binding of the drugs occurs inside the cortex, perhaps aided by the melanin present.[25]

The amount of drug needed can readily come from the environment. While some researchers have used extended periods of time for exposing hair to drug solutions, we have not. Generally, our exposure conditions have been between 1-10 µg/mL of cocaine in an aqueous media for 1-2 hours[26]. We have varied both the time and concentrations and have observed a linear increase in incorporation of cocaine with time and concentration. Is exposure to 1-10 µg of cocaine "excessive"? I think not. 100 mg of cocaine is considered a typical dose.[27] Levels of 1-10 µg are 1/100,000th – 1/10,000th of a single dose of cocaine and in amounts that one finds frequently in the environment. For example, we have been testing currency for drug contamination for a number of years. Generally, we try and test used currency.[28] Every dollar bill tested had cocaine present, generally in the 1-10 µg/bill range.[29] One had amounts > 300 µg/bill. Drugs are difficult to remove from money so that contamination by casual handling of money is unlikely.[30] Because "metabolites" are present on money, we hypothesize that their source is actually sweat or degradation.

It is well known that ethnic hair care products are often applied to African hair especially after chemical or heat straightening to keep the hair from curling due to moisture.[31] This is most typically done by African-American females.[32] These ethnic hair care products are basically oil or oil-glycerol mixtures. We have shown that in the case of the amine-containing drugs, these hair care products can enhance the uptake of drugs from the environment 500 fold.[33] Another aspect of African female hair care is that it is not washed frequently due to cosmetic reasons (*i.e.* you would need to straighten it again after washing or put back in hair extensions – both time consuming processes). Additionally, African hair tends to be drier than Caucasian hair and need not be washed as frequently as well as needing oil to keep it in place.

Genetics also plays a role as African hair is typically curly. If the popular culture values straight hair, then commercial businesses provide the means to achieve that goal in providing hair care products and extensions. Straightening products strip the cuticle (Figure 1a) from the hair and make it more porous to the environment (Figure 1b). Thus, a combination of genetics and culture of perceived beauty make African hair more susceptible to influx of drugs from the environment.

Besides allowing ready entry, ethnic hair care products can enhance the uptake from the environment. THC is well known to bind to oils. It is reasonable to assume (like shown for cocaine and amphetamines) that ethnic hair care products will concentrate THC from the environment and thereby basically apply a solution of THC to the hair until the hair is washed. Because of hygiene and application of oils (as mentioned above),

any solution of THC remains on the hair for a lengthy time compared to other groups. Time and higher concentrations increase the diffusion of THC into the hair. Additionally, the oil treatment provides the liquid vehicle that also facilitates this transfer. Of course, any individual could straighten their hair, apply oils, and wash it infrequently. It is just more culturally relevant to African-American females.

In summary, different hair "types" have different rates of contamination from the environment. Cosmetically treated hair, because of damage and residual chemicals, transferred drugs more readily then untreated hair. To the extent that African Americans more frequently treat their hair (for genetic and cultural reasons), they as a group would be more susceptible to environmental contamination and the resulting false positives and false accusations resulting from that contamination.

Lack of definitive markers of drug use – "metabolites"

THC is metabolized to a number of compounds in the human body through the liver enzymes cytochrome P450 oxidase system.[34] These enzymes are a superfamily (multiple forms) of monooxidase enzymes containing iron as a cofactor complexed in heme.[35] The major metabolites of THC are THC carboxylic acid, abbreviated THC-COOH, and 11-hydroxy THC, abbreviated THC-OH.[36] The metabolism of THC is done in a step-wise fashion. First THC is oxidized to THC-OH and then THC-OH is oxidized to THC-COOH. As THC and its metabolites are very lipophilic (not very water soluble), additional metabolism adds sugar residues (glucuronidation) to the THC-OH and THC-COOH metabolites.[37] These glucuronides are then excreted in urine. Many lipophilic drugs also follow this pathway.

After using marijuana, both THC[38], THC-OH, and THC-COOH appear in hair with the major compound being THC, with THC being present ~10-60x more than THC-COOH.[39,40,41,42,43] It is thought that analysis of THC-COOH, being a metabolite not considered to be present in the environment, would eliminate the concern that plagues hair analysis for other drug classes where the "metabolites" can be formed from environmental degradation of the parent drugs in the hair or contact with them in the environment.[44] Thus, elimination of environmental contamination is thought by many to be impossible for many drugs and therefore definitive use vs. exposure cannot be made by a positive hair sample only. This was eloquently expressed by Dr. Chatterton as:[45]

> "So, is external contamination still a debate? External contamination is a scientific fact; it happens; it is not for debate. We, the forensic scientists, must recognize this fact and consider all possible hypotheses and scenarios when offering an interpretation of the analytical results of hair analysis."

Principle scientists in some commercial laboratories have recognized this fact and readily admit that hair analysis measures exposure rather than only use.

Once THC and its decomposition products are incorporated into hair, they are difficult to remove.[46] Normal hygiene and many cosmetic treatments do not appear to affect their concentrations.[46] Even using a shampoo (Cannabio® Shampoo) with THC at trace levels can incorporate cannabinoids into hair that is not removable.[47] Interestingly,

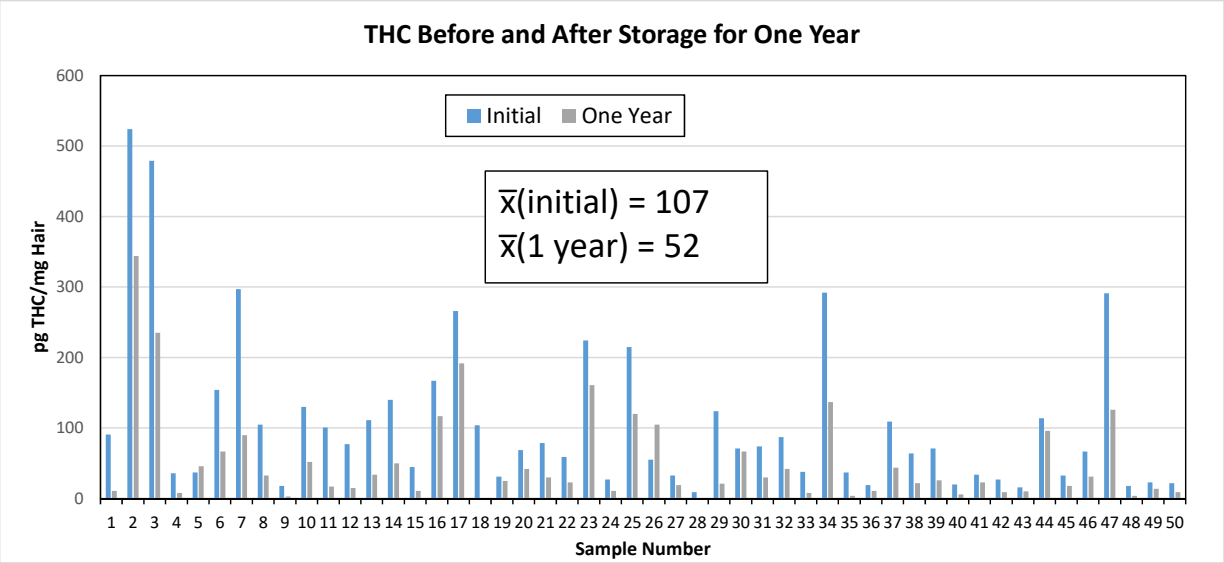
children, who are not expected to be active drug users, living in a drug using environment incorporate THC and show THC-COOH into their hair that cannot be decontaminated.[48,49,50] The cause of this contamination (absorption into the child or mere passive exposure on the surface) is still open debate in the scientific literature.

The metabolism and origin of most drugs of abuse in hair have been well studied. THC has not. It is generally believed that THC-COOH is considered to be a definitive metabolite and its presence demonstrates use of marijuana. But is THC-COOH a definitive metabolite of THC? Not really. THC is actually an unstable compound and decomposes on exposure to oxygen and light into a wide variety of uncharacterized materials. Interestingly, the major human metabolites of THC (and the ones we find in hair) are all oxidization products at an allylic position caused by removing hydrogen atoms. Allylic hydrogens are especially prone to non-specific oxidation from just exposure to oxygen in the air, perhaps catalyzed by light.[51] In the chemical synthesis of THC-COOH for the high-yield preparation of standards, oxidation can form THC-COOH.[52]

Non-specific production of THC-COOH from THC has been shown to occur over a decade ago. From unpublished work by Associated Pathologists Laboratories, they quantitated THC and THC-COOH in hair that was stored one year.[53] Figure 3 clearly shows that THC is unstable in hair upon storage with the majority of samples showing a profound decrease in THC over a one year storage. What is more telling is THC-COOH, the "metabolite" increases over time in the majority of the samples. Clearly this is not due to human metabolism as these are cut hair samples stored in a laboratory.[54] The logical conclusion is that a small fraction of THC is degrading to the specific compound THC-COOH (being tested) and the rest decomposing to unknown materials. There is some speculation that melanin may play a role in the degradation of THC as melanin is known to activate oxygen in a manner similar to Fenton oxidations.[51]

Officer Kennedy's hair was only tested for the presence of THC-COOH. Other materials must be present as the amounts indicated by the ELISA (the initial, general test) and GC/MS/MS (the specific confirmation test) do not agree. Knowing both materials may be helpful in distinguishing use from exposure in the decontamination as has been noted by others:

> "Although this is a specific metabolite (referring to THC-COOH), it is recommended that delta-9 THC be measured to determine contamination levels and external removal"[55]



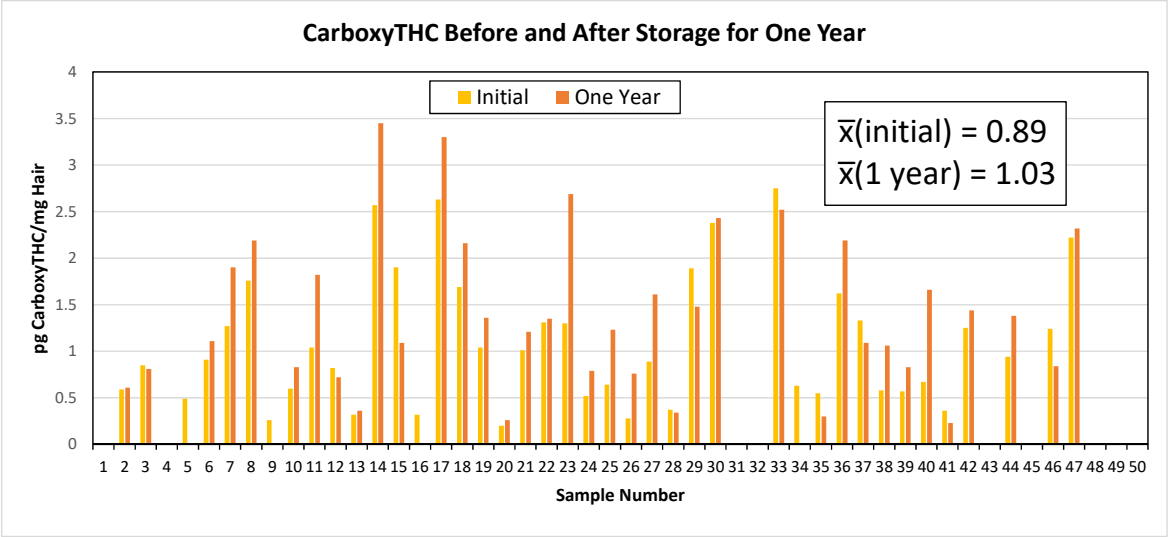


Figure 3 – Fate of THC and THC-COOH in hair from suspected users of marijuana after storage for one year. A few samples containing THC did not have THC-COOH above the LOD, assumed to be 0.3 pg/mg at that time. Study conducted by Associated Pathologists Laboratories and submitted to the Hair Testing Working Group as unpublished work. Data analyzed by myself.

Concerns about Omega Laboratories, Inc. Analysis of Officer Kennedy's Sample LAN #4831171.

Briefly, there are three broad steps to hair testing: (1) collection and submission to the laboratory, (2) screening at a given drug level normally using an immunoassay test. Immunoassays tend to be class-specific assays i.e. they will report a positive from a large number of related compounds. If a hair sample tests below an arbitrary level on the immunoassay screen, it is reported negative, and the sample is not tested further. (3) If the sample tests presumptive positive on the immunoassay screen, it is decontaminated, the drug extracted, derivatized to increase it detectability, and

analyzed by a specific technology based on mass spectrometry. If the sample is above an arbitrary level by the confirmation test, then the sample is reported positive for that drug.[56,57]

Analysis of THC and THC-COOH in hair is very difficult. Besides the instability of these materials, their concentrations from known users are at least 2000 times lower than cocaine, heroin, methamphetamine, and PCP and in general much more than that.[58] Additionally, THC and THC-COOH are sticky molecules that in these low concentrations bind to surfaces of analytic glassware and tend to be lost in the analysis. The more trace the analysis the more care must be taken by the laboratory to avoid false positives from contamination or incorrect procedures.

There were a number of issues with this analysis of this particular sample.[59] The page numbers in this discussion refer to this analysis. Unfortunately, very few of those concerns were alleviated by in deposition of Ms. Lauren Vinsick, the representative of Omega Laboratories, Inc.[60] (abbreviated as Omega, with transcript references as Vinsick, page:line) They are:

Incorrect sample length
Officer Kennedy's hair was tested at a length of 3.5 inches (Omega p. 12). This is quite long. Hair is considered to grow 0.8-1.3 cm/month and most laboratories use 1.5 cm (1.2") for testing. Omega cuts the hair to approximately that length if it is head hair (Vinsick 22:16), which they should have considered this hair sample to be head hair (Vinsick 24:11). Having a uniform hair length treats all individuals equally as hair can reflect use amount, contamination opportunity, and time.[61] Having a longer sample length of hair (and hence longer time) both allows for more past use to be detected and contamination to occur that can be confused with use. As described in more length in an endnote (see endnote 56), SAMSHA regulates federal drug testing but not commercial testing, which can have any standards. In their proposed guidelines (which have never been finalized) SAMSHA requires hair to be 1.5" or less.[62]

No decontamination in initial screening test
Omega uses a simple extraction (Omega p. 13) with acidified methanol for the initial immunoassay testing.[63] This process does allow extraction of most drug classes so that the drug of interest can be rapidly identified for confirmation testing (which requires different and cumbersome procedures for each drug class). However, because Omega does not decontaminate the hair, hair that has been treated with oils (as was Officer Kennedy's) hair can confuse the immunoassay and can produce false positives.[64]

Insufficient precision in sample weights
A review of Omega analysis shows what appears to be weights to one unit – either 10 mg or 20 mg of hair. When asked about these units Ms. Vinsick (Vinsick 54:7) indicated that the weights were to one significant figure. In my opinion that is poor analytical chemistry both in the analysis and the reporting of the data.[65] In the initial immunoassay screening test, Omega appears to weighs out nominally 10 mg of hair. Since this is done by guessing that it is around 10 mg, it could be just as well 15 mg of hair. The

more hair you employ that greater the amount of drug that will be extracted. Not knowing this weight accurately makes any cut-off meaningless if the sample is near that value, as was Officer Kennedy's sample, which could in reality be negative. Any reputable laboratory would normalize the values obtained to the quantity of hair used before determining if it were positive. Clearly Omega must just assume 10 mg of hair in their calculations.[66] This error is also compounded in the confirmation test where 20 mg of hair is assumed (Omega p. 60). Clearly, when they have values lower than 20 (i.e. 10 in the example), they normalize the results by that number. Officer Kennedy's hair was assumed to be 20 and no math was used. Like the immunoassay screen, this number could be wrong by 50 % or more and still meet their protocol.

Insufficient precision in the initial test

Officer Kennedy's initial screening test compares her sample to standards run at the same time. If her sample has values below the standard, it is considered positive (the test produces inverse numbers)[67]. Two standards at the cut-off are run and the results averaged. The values were: 1.629 & 1.721 for an average of 1.675. Officer Kennedy's sample was 1.671. Thus, the sample was negative by the first standard but positive by the second and positive by the average. The error if calculated based on raw values was 5.65%, which is somewhat larger than Omega's FDA clearance on this assay, but reasonable.[68] Interestingly, if you were to use all the data in the calibration curve (that helps increase the precision), the sample would have been below the cut-off and reported negative.

What is being tested via the screening test (ELISA)?

Ms. Vinsick (Vinsick 43:19) was unaware of the cross-reactivity of their initial screening test. That is reasonable. However, according to Omega's FDA clearance data, their screening test is normalized to THC-COOH at 100%.[69] THC cross-reacts to only 2%, which implies that to reach the 1 pg/mg cut-off for THC-COOH, THC would need to be presents at 50 times high concentration or 50 pg/mg.[70] Other related compounds also have cross reactivity but THC is the major component in hair. Omega does not measure the THC content of hair. Also, one can tell that the initial screening test does not measure only THC-COOH as the specific confirmation test found 5 fold less THC-COOH present than the screening test. Hair testing for THC is one of the few cases where the screening test has a poor correlation with the confirmation test because they do not measure the same thing.[71,72] I should note that the City Directive 6.5 (City 303) states: "To ensure optimum accuracy, the tests will be drug-specific. The drug abuse screening test will consist of two tests: …" The ELISA tests using in the initial screening by Omega clearly does not meet the requirement of being drug specific.

Lack of decontamination procedure

One of the major concerns of hair testing is what does it measure? – use or mere exposure. Effective decontamination procedures help distinguish the use vs. exposure if laboratories would only test their test.[73] Omega's decontamination is woefully inadequate in that they rinse the hair for 5 seconds in methanol.[74] If I assume that this is a misprint and it actually means 5 minutes, I would still consider that amount of

decontamination inadequate. Additionally, Ms. Vinsick could provide no in-house evaluations of decontamination studies.

Inaccurate internal standard additions

To measure the amount of THC-COOH by mass spectrometry a known amount of a deuterated internal standard is added to the sample as soon as possible in the analysis procedure. Deuterium is used because it produces a compound that is chemically similar to the analyte in question but can be distinguished by its mass spectrometric signature. By adding the standard early in the analysis, anything that happens to the sample will be compensated. For example, if half the sample were lost, half the internal standard would also be lost and the ratio of analyte to internal standard would remain the same. The laboratory documentation implies that the same amounts of internal standard are added to all samples. This was confirmed by Ms. Vinsick (Vinsick 62:2). However, a casual glance at the results for the calibration curve and Officer Kennedy's sample shows that something is amiss. All the responses (n= 11) for internal standards in the calibration curve are between 16K and 32K, whereas the standard in Officer Kennedy's sample reads 147K. The source of this over five-fold discrepancy is unknown. This cannot be true if all the samples had the same amount of internal standard added.[75]

Use of conventional standard methods linear line

Omega takes pains to generate a calibration curve (p. 64) and it looks quite impressive. Then they use this curve in quantitating the samples. It is common practice is to use the calibration curve's slope to modify the raw data generated by the instrument to produce a more accurate result.[76]

Understanding of the confirmation procedure

The chemistry of Omega's analysis does not appear to be understood by the laboratory personnel. The documentation (p. 58) mentions to add 75 µL of PFAA. When asked what PFAA stands for, Ms. Vinsick (Vinsick 50:19) states Pentafluroacetic anhydride, which does not exist.[77] What she means is pentafluoropropionic anhydride.[78] In my teaching of students and contract personnel analytic procedures, I emphasize the science behind the analysis so that they can recognize when things go wrong.

Inconsistences with other analysis

It is my understanding that after being informed of her positive test, Officer Kennedy had an independent analysis of another sample of hair taken eight days later and sent to United States Drug Testing Laboratories (USDTL). According to the report (City Bates 0979) the sample tested negative in the screening test at a sensitivity identical to that used by Omega. As the initial test was negative, the sample did not go onto confirmation. I requested the full litigation package to allow careful examination of the raw data. If there is any THC reactive materials present they are at least half of the cut-off level of 1 pg/mg of hair. What could account for this discrepancy between USDTL negative and Omega's positive? USDTL indicates in their collection video for hair that

the collector should cut the hair to a length of 1.5".[79] Shorter hair allows for less possibility of environmental contamination. It is my understanding that the collection process followed the video – decontamination, gloves, and cutting hair to a fixed length. USDTL decontaminates the hair before they perform the screening test.[80] Their decontamination likely removals only superficial contamination. It would also remove hair treatment products such as oils that would be in this superficial contamination and prevent them from interfering with the initial ELISA screening test generating a false positive result.

Importantly, Officer Kennedy has testified that she treats the nape hair (which was tested by Omega) with "Wild Growth" (Kennedy 35:20) whereas she treats the top of her hair (which was test by USDTL) with less oil and a different brand "Cactus Oil" (Kennedy 66:23).[81] As ethnic hair care products have been shown to absorb nitrogen-containing drugs from the environment and reasonably be expected to do the same for THC (as discussed above), this puts the Omega hair sample at a greater risk of contamination and false positives because (1) more oil is present and (2) the oil was not removed by Omega before testing the hair.

The time window for detection of marijuana use via urinalysis is the longest of all drug classes. For heavy users, the window of detection can span many days. Urine testing detection ability of marijuana use was similar to hair testing (Figure 4).[82] The data in Figure 4 may be skewed to false negative urine samples due to the nature of pre-employment testing which comprise the majority of these samples.

I note that data from the Philadelphia Police Departments own program showed that there were six positive urine marijuana tests from 2014-2019 whereas there were four positive hair tests (including the one from this present case). The correlation of hair and urine was not available in the data provided by the City.[83]

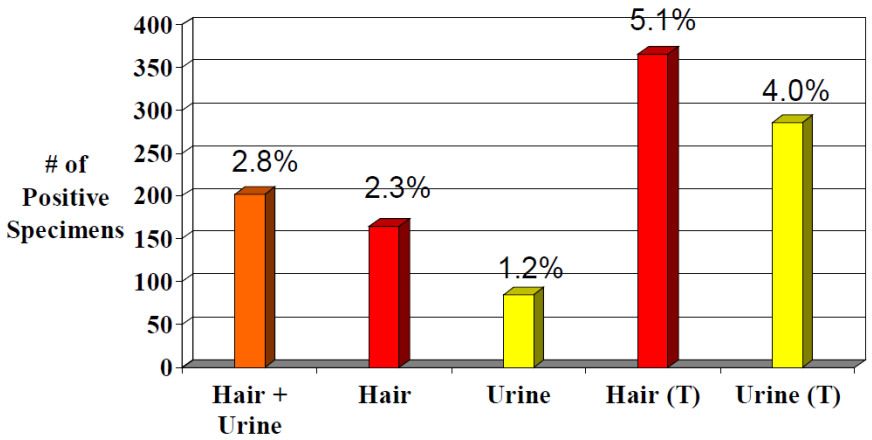


Figure 4 – A comparison between urine and hair testing. From: James A. Bourland, "Practical Aspects of Drug Testing in Human Hair - Laboratory Perspective", presented to the Drug Testing Advisory Board, July 2013. The hair and urine positive are positive in only that matrix. The totals with either matrix are labeled with the (T). The majority (70.3%) of these specimens are pre-employment samples, where the individual often knows they are going to be tested so they can avoid detection by abstinence. The cut-off levels for urine were not

specified. A lower level would produce more urine positives. Although presented in 2013, the samples and testing data were from 2001 and consisted of about 7000 matched samples.

A urine specimen for Officer Kennedy taken at the same time by the Philadelphia Police Department tested negative. Like the hair sample, I requested the full litigation package from Drug Scan (Specimen ID: 510026042, collected 3-20-19). Careful examination of the raw data does not indicate even the hint of THC metabolites at the lowest levels of testing. Furthermore, an additional urine sample collected on the initiative of Officer Kennedy was tested by LabCorp and found negative.[84] I also requested the full litigation package for this sample but only received a summary that basically indicated that the sample was normal and negative. All the samples (hair and urine) appeared normal with no hint of evasion of the drug test.

The easiest way to reconcile these disparate analyses is to invoke passive exposure and thereby a false positive in the Omega hair sample.

Alternatives to use of hair testing in a drug-deterrent program

In a safety-sensitive job drug use can be a concern, and effective drug testing deters drug use. The Philadelphia Police Department employs drug testing on a random basis with both hair and urine as the test matrices. Random testing is more effective than scheduled testing as employed by other police departments and they should be commended for that part of their approach. Some drugs are more readily detected by hair testing than urinalysis. As used by the Philadelphia Police Department, hair testing could identify individuals who have used drugs and those that have been merely exposed to drugs. One cannot determine drug use from a single test. For example with cocaine, it has been shown that FBI agents have cocaine positive hair even after decontamination.[85] It is interesting that the Philadelphia Police Department takes both urine and hair, with hair being randomly tested in about 10% of the total samples and urine tested with all the samples. Either sample being positive is grounds for dismissal.

The Philadelphia Police Department could use a more enlightened approach to drug testing to ensure a drug-free workforce. For example, they should take NO adverse action based solely on a hair test as hair measures exposure to drugs. The hair test would only be used to classify individuals into those whose job, contacts, hair type, and cosmetic practices, make them suitable for testing by hair analysis. If an individual was detected to be positive OR exposed to drugs by a hair test, then that individual would be placed in a frequent, random urinalysis program.[86] Only if that individual were positive by urinalysis, would adverse action be taken.[87] As the Philadelphia Police Department already uses urinalysis as their major drug testing matrix, a few extra samples should not be a financial or logistic burden, especially when compared to replacing a trained police officer.

Conclusions

Hair testing measures exposure to drugs. How drugs appear in hair from use or exposure cannot be determined by a single test. There are no unique metabolites of most drugs to definitively determine if that exposure was due to use or external contact with drugs or drug residues.

Research suggests that African Americans are disparately impacted by false accusations of drug use (false positive from testing) when hair testing for drugs is employed. Genetics and cultural differences in how hair is cosmetically treated (imposed by those genetics) provides especially African Americans with hair that is more susceptible to contamination from the environment and thereby false accusations of drug use from mere drug exposure.

Because of Officer Kennedy's African hair type and cosmetic preferences, it is reasonable scientific conclusion that her positive hair test was a false positive. Furthermore assuming a correct laboratory analysis (which isn't a given), the false positive was due to exposure to marijuana and that exposure is the source of the THC "metabolite" THC-COOH in her hair.

I base this conclusion on several facts:

- It is my understanding that Officer Kennedy was exposed to sources of THC in her job. Additionally, Officer Kennedy treated her hair with oils that would allow concentration and binding of THC from the environment and that exposure is greatly enhanced by the hair treatments that African Americans use.
- The laboratory decontamination procedure is woefully inadequate and relies upon the presence of unique "metabolites" to demonstrate marijuana use. Scientific evidence exists that show that THC is unstable in hair and decomposes to THC-COOH upon storage in benign laboratory conditions. Decomposition upon exposure in hair to the environmental conditions experienced in everyday life is unknown but should occur even more readily.
- Very little is known about passive exposure to THC. However, children living in a drug using environment test positive for THC-COOH. The source of this "metabolite" in young children is still an open question, but decomposition could be the rationale for finding THC-COOH in the hair of children. THC-COOH is the purportedly definitive "metabolite" that indicates Officer Kennedy to be a marijuana user.
- The actual THC level in Officer Kennedy's hair was not measured and the ratio of THC to THC-COOH could not be determined.
- No consensus exists in the scientific community as to what a positive hair test means - Is it use or contamination? Nor what levels constitute a positive result.
- Officer Kennedy's hair was not cut to a defined length as others samples. The time frame based on the length of her hair sample was 2-7x longer than other subjects. Longer time frames allow more time for exposure and more time for "metabolites" to form after the exposure.

- THC and its metabolites do not bind well to hair and are at 2000x lower levels than other drugs. This makes their analysis challenging. To generate any positive results from known marijuana users, the analytical technology needs to be stretched to its limits.
- The laboratory confirmation analysis had a number of substantial defects and unknowns that calls into question their quantitation of THC-COOH.
- An independent analysis of another sample of hair taken a few days later tested negative, and careful examination of the raw data does not indicate the presence of substantial amounts of THC or related materials. THC metabolites have been shown to be stable to many removal techniques. *i.e.* if Officer Kennedy had tried to generate a false negative on a second sample by cosmetic methods, she would have likely failed.
- Officer Kennedy was randomly selected for drug testing and thus had no opportunity to adulterate her urine or hair specimens.
- In random studies, detection of marijuana use via hair testing produces a similar positive rate than urinalysis. A urine specimen for Officer Kennedy taken at the same time tested negative and careful examination of the raw data does not indicate even the hint of the presence of THC metabolites. Additionally, the sample appeared normal with no physical dilution (i.e. no attempt to hide marijuana use – in fact the sample was somewhat concentrated as indicated by the creatinine level).

I have rendered all the above opinions and conclusions to a reasonable degree of scientific certainty; and, in forming my opinion and conclusions, I have relied on documents and scientific techniques that are reasonable, customary, and necessary in my field of drug-testing expertise.

References and Notes

[1] This affidavit is being given in my capacity as a private citizen. The opinions contained herein represent my own views and do not necessarily represent the opinions or policies of the Department of the Navy or of the U.S. Government.

[2] These awards are given annually. The Naval Research Laboratory has approximately 1000 technical and 2000 support employees and the Chemistry Division has about 150 employees. The Edison Patent Awards are given for the 1-3 best patents of the year in the whole Naval Research Laboratory. The Berman Awards are given for the two best technical papers – applied and basic – in each Division.

[3] I was compensated for preparation of this report at $227.56/hr. This is the rate that a private company would need to pay my employer for my services. I typically limit the amount so as not to have a claim of overbilling.

[4] This concept in hair analysis for drugs may have been novel at the time of first use by Werner Baumgartner but was well known for heavy metals, such as zinc and lead. Deliberately contaminated hair with lead could not be decontaminated. See: P. Manson, “Hair analysis – a critical review”, *Can. Med. Assoc.*, **133** (1985) 186-187. The problem with external contamination for metals has not been resolved to date and is widely discussed in the technical literature.

[5] The Philadelphia Police Department tests approximately 4000 samples/year mostly at random. Of those individuals chosen, at random, 90% are via urinalysis and the remaining are by both urinalysis and hair testing. From the Compressed Transcript of the Testimony of Lieutenant John Kay, 12/18/19 Case: Green v. City of Philadelphia, et al., p. 13, line 10.

[6] Actually, this was two separate studies. The first study produced such surprisingly high results that the protocol was repeated. The second study confirmed the preliminary results.

[7] The commercial laboratory agreed in most samples for our analysis except one, which was much higher. In science you only need one counter example to call into question your approach to problem solving. This was the one example that caused us to reconsider our analytical approach. After much work, we discovered that our analysis method UNDER estimated the level of cocaine in some hair types. Therefore, some of the children would have been even more positive than was reported. We have since scrapped the original procedure and developed an alternative.

[8] One may ask, if not ingestion, what could cause a one-year old have so much drug present? A simple possibility is that these children were bottle-fed. During bottle-feeding, a mother supports the head of the baby with the palm of her hand. A cocaine-using mother, is likely to have contamination on her hands from use as well as handling cocaine. Thus, the baby's hair would be rubbed repeatedly with cocaine from the sweat of the mother, allowing the transfer and incorporation of cocaine and metabolites.

[9] With this large amount of cocaine present "microingestion" should not even be a consideration.

[10] For example see: Lewis, D., C. Moore, P. Morrissey and J. Leikin, "Determination of drug exposure using hair: application to child protective cases", *Forensic Science International*, **84** (1997) 123-128.

[11] See: Guido Romano, Nunziata Barbera, and Isabella Lombardo, "Hair testing for drugs of abuse: evaluation of external cocaine contamination and risk of false positives", *Forensic Science International*, **123** (2001) 119-129. Although not explicitly stated, I assume that the volunteers in this study were actually the authors. In that way, they could be sure that drug use did not occur during the study. Additionally, the hair care of the subjects could be closely monitored. Although none reported unusual cosmetic treatment, one participant washed his/her hair in vinegar. I would never have considered this washing hair with vinegar "normal", which reinforces that cultural differences (in this case participants from Italy), influence hair care and make studying "normal" hygiene difficult.

[12] Guido Romano, Nunziata Barbera, Giorgio Spadaro, and Vincenzo Valenti, "Determination of drugs of abuse in hair: evaluation of external heroin contamination and risk of false positives", *Forensic Science International*, **131** (2003) 98-102.

[13] Hair also swells in high humidity environments and in the presence of sweat. Since 1775, hygrometers have been constructed using the swelling properties of hair to measure humidity.

[14] From an article in *Science News*.

[15] GL Henderson, MR Harkey, C Zhou, RT Jones, and P. Jacob, III, "incorporation of isotopically labeled cocaine into human hair: race as a factor", *J. Analytical Toxicology*, **22** (1998) 156-185. The authors suggest that: "…there may be a racial bias in the incorporation of cocaine into human hair."

[16] D.E. Rollins, D.G. Wilkins, A. Mizuno, M.H. Slawson, and C.R. Borges, "The role of pigmentation in the disposition of drugs of abuse in human hair", Clinical Pharmacology & Therapeutics Online.

[17] D.G. Wilkins, A. Mizuno, C.R. Borges, M.H. Slawson, and D.E. Rollins, "Ofloxacin as a reference marker in hair of various colors", *J. Analytical Toxicology*, **27** (2003) 149-155.

[18] Stacy J. Smeal, Diana G. Wilkins, and Douglas E. Rollins, "The Incorporation of Delta-9-tetrahydrocannabinol and Its Metabolite, 11-nor-9-carboxy-delta-9-tetrahydrocannabinol, into Hair", *J Anal Toxicol*ogy, **30** (2005) 139–140.

[19] Stacy Janine Smeal, "Mechanism of Cannabinoid Incorporation in Hair", a dissertation submitted to the faculty of The University of Utah in partial fulfillment of the requirements for the degree of Doctor of Philosophy, May 2007.

[20] See: David A. Kidwell, Emmelene H. Lee, and Saundra F. DeLauder, "Evidence for bias in hair testing and procedures to correct bias", *Forensic Science International*, **107** (2000) 39–61. Large scale studies that purport to show that bias does not exist are not relevant. If bias occurs, it is probably undetectable in any large population study. This differential detection is really a measure of the cut-off of the assay. In any uncontrolled study (where the dose is not administered), drug use is rarely, very sporadic. In these cases, the use will be high enough so that all hair types or races will be positive. Although it may be a concern that if two individuals, African American and Caucasian, used the same amount of drug and only the African American was detectable by hair analysis, they still need to be a drug user.

[21] This data was attached to a letter received January 22, 2001 from Werner Baumgartner and supplied to the members of the Hair Testing Working Group.

[22] Rate is an important parameter. To prepare hair samples that mimic hair from real users, the Research Triangle Institute (RTI) exposes hair for one week to drugs and then washes the hair extensively, (to remove external contamination). I would agree that a one-week exposure is excessive and probably unnecessary. However, it appears that this very long exposure breaks down the kinetic barrier to drug

diffusion and provides hair with a uniform drug content – just what is needed for standards. RTI apparently has not varied this procedure to determine the minimum criteria for exposure.

[23] David A. Kidwell, Frederick P. Smith, and Arica R. Shepherd, "Ethnic hair care products may increase false positives in hair drug testing", *Forensic Science International*, **257** (2015)160-164.

[24] David A. Kidwell and Fredrick P. Smith, "Susceptibility of PharmChek™ Drugs of Abuse Patch to Environmental Contamination", *Forensic Science International*, **116** (2001) 89-106. In this case, drugs were transferred from skin, which contains similar proteins to hair, to a pad placed on the surface. This transfer was approximately two-fold better with glycerol in the pad than sweat alone. Part of the reason is that glycerol remains (does not dry-out) whereas the presence of sweat is transient.

[25] Most authors, including us, remove this cosmetic treatment before laboratory contamination experiments are done. This is partly to better control the procedure. Different laboratory pretreatments of the hair can account for different ordering of hair types in their uptake of drugs. Additionally, there is no hair available to provide standards, making comparisons between laboratories difficult.

[26] We have used times as short as five minutes and have observed incorporation of cocaine.

[27] For non-novice users, one needs to inject about 30 mg of pure cocaine to produce an effect. Intranasal or oral ingestion is about three times less effective and consequently requires more drug.

[28] These studies obtained money from the Naval Research Laboratory Federal Credit Union. This money comes from the Baltimore Federal Reserve Bank. Baltimore has a high incidence of cocaine use, which may account for the large positive rate of currency from that source.

[29] The source of drugs on money is not clear. Based on finding metabolites, I believe that much comes from the sweat of drug users. Cocaine likely binds to the fibers or ink of the currency and the money MUST be extracted to efficiently determine the amount present. It is unlikely present as particles unless closely associated with drug use.

[30] Rubbing money between the palms of the hands does not transfer much of the drug present. However, handling the money with damp palms can transfer 100-300 ng of cocaine from the bill. Of course, one would then need to transfer this drug to one's hair. I believe that this transfer is highly unlikely, but not impossible.

[31] I.E. Roseborough and A.J. McMichael, "Hair Care Practices in African-American Patients", *Semin. Cutan. Med. Surg.*, **28** (2009) 103-108.

[32] A.J McMichael, "Hair Breakage in Normal and Weathered Hair: Focus on the Black Patient", *Journal of Investigative Dermatology Symposium Proceedings,* **12** (2007) 6–9.

[33] David A. Kidwell, Frederick P. Smith, and Arica R. Shepherd, "Ethnic hair care products may increase false positives in hair drug testing", *Forensic Science International*, **257** (2015)160-164.

[34] Tamihide Matsunaga, Nobuyuki Kishi, Shinsuke Higuchi, Kazuhito Watanabe, Tohru Ohshima, and Ikuo Yamamoto, "CYP3A4 Is A Major Isoform Responsible for Oxidation of 7-Hydroxy-Δ8-Tetrahydrocannabinol To 7-Oxo-Δ8-Tetrahydrocannabinol In Human Liver Microsomes", *Drug Metabolism and Disposition*, **28** (2000) 1291.

[35] https://en.wikipedia.org/wiki/Cytochrome_P450

[36] I am ignoring the exact chemical nomenclature as the IUPAC names are long and it is irreverent to the discussion at hand.

[37] Eugene W. Schwilke, David M. Schwope, Erin L. Karschner, Ross H. Lowe, William D. Darwin, Deanna L. Kelly, Robert S. Goodwin, David A. Gorelick, and Marilyn A. Huestis, "Δ9-Tetrahydrocannabinol (THC), 11-Hydroxy-THC, and 11-Nor-9-carboxy-THC Plasma Pharmacokinetics during and after Continuous High-Dose Oral THC", *Clin Chem.,* **55** (2009) 2180–2189.

[38] Interestingly, free THC is not present in fresh marijuana, but it is produced as a precursor called THC-A, which is physiologically inactive. THC-A must be heated to make free THC. Thus ingesting marijuana without heating (by baking for example), has little or no effect. See: Franz E. Dussy, Cornelia Hamberg, Marco Luginbuhl, Thomas Schwerzmann, and Thomas A. Briellmann, "Isolation of Δ9-THCA-A from hemp and analytical aspects concerning the determination of Δ9-THC in cannabis products", *Forensic Science International,* **149** (2005) 3-10.

[39] Maria Joao Baptista, Paula Venancio Monsanto, Estela Gouveia Pinho Marques, Ana Bermejo, Sofia Avila, Alice Martelo Castanheira, Claudia Margalho, Mario Barroso, and Duarte Nuno Vieira, "Hair analysis for D9-THC, D9-THC-COOH, CBN and CBD, by GC/MS-EI Comparison with GC/MS-NCI for D9-THC-COOH", *Forensic Science International,* **128** (2002) 66–78.

[40]Michael Uhl and Hans Sachs, "Cannabinoids in hair: strategy to prove marijuana/hashish consumption", *Forensic Science International*, **145** (2004) 143-147.

[41] Gisela Skopp, Peter Strohbeck-Kuehner, Karl Mann, and Derik Hermann, "Deposition of cannabinoids in hair after long-term use of cannabis", *Forensic Science International* **170** (2007) 46-50.
[42] Diana Wilkins, Heather Haughey, Edward Cone, Marilyn Huestis, Rodger Foltz, and Douglas Rollins, "Quantitative Analysis of THC, 11-OH-THC, and THCCOOH in Human Hair by Negative Ion Chemical Ionization Mass Spectrometry", *Journal of Analytical Toxicology,* **19** (1995) 483.
[43] Abstract from: Xiang Ping, Shen Min, Shen Bao-hua, Liu Wei, Bu Jun, and Wu Hejian, "Simultaneous quantification of cannabinoids and the major metabolite, THC-COOH in human hair", *Journal of Forensic Medicine*, **18** (2002) 216-219 at http://en.cnki.com.cn/Article_en/CJFDTotal-FYXZ200204008.htm. More data is in her thesis.
[44] Even with definitive "metabolites" that are absent from the environment (if they exist), one cannot exclude transfer of the metabolites from contact with a drug user or objects they touched. There is no indication that this occurred in the present case.
[45] Craig Chatterton, " External Contamination: Still a Debate?", in **Hair Analysis in Clinical and Forensic Toxicology**, Pascal Kintz, Alberto Salomone, and Marco Vincenti, eds., 2015, Elsevier, Amsterdam, pps. 47-70.
[46] Virginia Hill, Psychemedics Corporation FDA 510K Summary for their ELISA test for marijuana in hair, May 1, 2012, 510K Number: k1 11929. Submitted By: Psychemedics Corporation.
[47] Although the shampoo contained THC, it had more of CBD and CBN, which are related compounds in marijuana. These materials were only in trace amounts compared to marijuana so one would not expect to find much incorporated into the hair. THC was not detected but the other two compounds were. This may be due to insufficient sensitivity of the instrumentation at that time. See: Vincent Cirimele, Pascal Kintz, Carole Jamey, and Bertrand Ludes, "Are Cannabinoids Detected in Hair After Washing with Cannabio Shampoo?", *Journal of Analytical Toxicology*, **23** (1999) 349.
[48] Fritz Pragst, Franziska Krumbiegel, Denise Thurmann, Lena Westendorf, Maximilian Methling, André Niebel, and Sven Hartwig, "Hair analysis of more than 140 families with drug consuming parents. Comparison between hair results from adults and their children", *Forensic Science International*, **297** (2019) 161-170.
[49] Pascal Kintz, Alice Ameline, Aude Eibel, Laurie Gheddar, Emilie Feisthauer, Annie Geraut, Laurent Berthelon, Audrey Farrugia, and Jean-Sebastien Raul, "Interpretation of Cannabis Findings in the Hair of Very Young Children: Mission Impossible", from PMID: 29189142 DOI: 10.2174/1389201019666171129180206 *Curr. Pharm. Biotechnol*., **18** (2017) 791-795.
[50] Bjoern Moosmann, Nadine Roth, and Volker Auwärter, "Finding cannabinoids in hair does not prove cannabis consumption", *Scientific Reports,* **5** (2015) Article number: 14906.
[51] Gisela Skopp, Lucia Potsch, and Martin Mauden, "Stability of Cannabinoids in Hair Samples Exposed to Sunlight", *Clinical Chemistry***, 46** (2000) 1846. They did not measure THC-COOH production. Instead, they used CBN as a marker of degradation. THC decreased to undetectable after 10 weeks of exposure to light in many of the hair samples studied.
[52] I am NOT suggesting that chemical oxidation by applied regents had occurred with Officer Kennedy's hair. That is highly unlikely as she is not known to chemically treat her hair with bleach or dyes. However, I point out that this position of the THC ring is readily susceptible to oxidation and that only a trace fraction of the THC that could be present for environmental exposure need be converted to generate a false positive (as THC-COOH is so much lower concentration than THC). For examples of high-yield (as opposed to trace) chemical oxidation see: Craig Siegel, Patrick M. Gordon, David B. Uliss, G. Richard Handrick, Haldean C. Dalzell, and Raj. K. Razdan, "Synthesis of Racemic and Optically Active A9-Tetrahydrocannabinol (THC) Metabolites", *J. Org. Chem.*, **56** (1991) 6865. Craig Siegel, Patrick M. Gordon, and Raj K. Razdan, "Studies on the Synthesis of (-)-1l-Nor-9-carboxy-J9-Tetrahydrocannabinol (THC) and Related Compounds: An Improved Oxidative Procedure", *Synthesis*, (1991) 851. Morten Karlsen, Huiling Liu, Jon Eigill Johansen and Bård Helge Hoff, "Synthesis of [13C4]-labeled Δ9-Tetrahydrocannabinol and 11-nor-9-Carboxy-Δ9-tetrahydrocannabinol as Internal Standards for Reducing Ion Suppressing/Alteration Effects in LC/MS-MS Quantification", *Molecules*, **19** (2014) 13526.
[53] This data set was shown to the Hair Testing Working Group in January 2001.
[54] The data set at my disposal did not indicate storage conditions. I assume that this was normal storage conditions – *i.e.* either under refrigeration or in a box on a shelf.
[55] Xiang Ping, "Hair Analysis for Drugs of Abuse", a thesis submitted to the University of Central Lancashire in fulfillment of the requirement for the degree of PhD, March 2011.

[56] The criteria for calling a sample positive is left to the laboratory. There are no U.S. Government standards as the Substance Abuse and Mental Health Services Administration (SAMSHA) has never approved guidelines for testing of drugs in hair. Guidelines were proposed in 2004 but never finalized. Additionally, as the testing in the present case is not regulated by SAMSHA, the laboratory need not follow SAMSHA rules even if they did exist (i.e. they can make-up whatever they want).
[57] I do not believe that HHS certifies hair testing laboratories. Thus, it is not clear how Omega meets the requirements of the MOU (City 316) which states: "The City shall have the right to send obtained samples to the city designated/contracted qualified medical laboratory that is certified by the United States Department of Health and Human Services (USDHHS) or approved by the World Anti-Doping Agency (WADA)". See Omega p.6 for their certifications. One could assume that CLIA certification meets the requirements for urine testing, but I am not aware of the requirements for hair testing. Drugscan is the contract laboratory for urine testing, and according to their website they are SAMHSA certified for urine testing. See: https://drugscan.com/who-we-are/quality-assurance
[58] Most drugs are fairly stable in hair for long periods of times. Metabolites may form due to environmental degradation but these can be examined as well as the parent compound. THC, on the other hand, decomposes in hair to unknown materials. Thus, the low levels after use may be partially due to it decomposing and thereby disappearing after it is incorporated into the hair while the hair is on the head of a subject. That view is support by a study looking at sectional analysis of the hair where larger concentrations were found at the root vs. distal ends (the root being more recent growth). See: Eunyoung Han, Hwakyung Choi, Sangki Lee, Heesun Chung, and Joon Myong Song, "A study on the concentrations of 11-nor-D9 -tetrahydrocannabinol-9-carboxylic acid (THCCOOH) in hair root and whole hair", *Forensic Science International*, **210** (2011) 201-205.
[59] Laboratory Documentation Package, Laboratory accession number: 03446937 linked to Officer Kennedy in this present case and certified accurate by Laboratory Director David Engelhart, Ph.D.
[60] Information from Compressed Transcript of the Testimony of LAUREN VINSICK, 5/27/20
Case: Kennedy v. City of Philadelphia, et al.
[61] I use the word "can" as it may reflect usage patterns and time. However, external contamination can confuse these issues.
[62] See: Substance Abuse and Mental Health Services Administration, "Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing Programs" Federal Register: April 13, 2004 (Volume 69, Number 71), Page: 19673-19732.
[63] The ability to extract broad classes of drugs and metabolites with acidified methanol is not clear, but I will not discuss that further. Omega's FDA clearance for their THCCOOH ELISA test from 2012 (K122759) states: "Proprietary and patent pending method of pulverizing hair vs cutting the hair into small segments prior to acid methanol extraction. This improved extraction times without loss of efficiency." They do not appear to use that extraction method on Officer Kennedy's hair.
[64] For an example of an extensive wash procedure before initial testing see: E. Han, E. Miller, J. Lee, Y. Park, M. Lim, H. Chung, F.M. Wylie, and J.S. Oliver, "Validation of the Immunalysis® Microplate ELISA for the detection of Methamphetamine in hair", *J. Analytical Toxicology,* **30** (2006) 380–385. A less extensive wash before ELISA testing may be found at: Ronald Agius and Thomas Nadulski, "Utility of ELISA screening for the monitoring of abstinence from illegal and legal drugs in hair and urine", www.drugtestinganalysis.com) DOI 10.1002/dta.164
[65] Basically, it is a tenant in analytical chemistry that you report results with a precision of the least precise step (it is more complicated with dividing and multiplying numbers). If the hair weight is only known to one significant figure, then the results should also be reported to the same precision. Instead, they reported the results of Officer Kennedy's specimen as 1.00 pg/mg or to three significant figures. For an extensive (a little too extensive for my tastes) statistical analysis of data see: Eunyoung Han, Wonkyung Yang, Sooyeun Lee, Eunmi Kim, Sangwhan In, Hwakyung Choi, Sangki Lee, Heesun Chung, and Joon myong Song, "Establishment of the measurement uncertainty of 11-nor-D9-tetrahydrocannabinol-9-carboxylic acid in hair", *Forensic Science International* **206** (2011) e85–e92.
[66] Omega reports cut-off values as quantity of drug per mg of hair. How can you report those numbers if you do not know the weight of the hair?
[67] I could discuss ELISA tests at length, as I have designed some for specialized testing. However, I will use general concepts in this discussion because the mechanism of how ELISA tests work is not important in understanding the results.

[68] I note that the other standards were also run in duplicate and their raw errors varied between 0.4 and 1.1%.
[69] Omega Hair Drug Screening Assay for THCA, FDA K122759, December 4, 2012. Omega appears to use the International Diagnostics Systems Inc. ELISA test. IDS had been purchased by Neogen and Neogen still distributes ELISA kits for the forensic analysis of THC. Interestingly, according to their website, the THC hair test is NOT approved for distribution in the US. See: https://toxicology.neogen.com/en/thc Omega may be using the THC urine test based on the reported cross-reactivity on the Neogen website being most similar (but not identical – cross reactivity does change) to that reported by Omega in their FDA clearance document.
[70] This calculation gets complicated because the specific assay found THC-COOH at 0.28 pg/mg (ignoring the poor quantitation and significant figures). Thus, the math should be (1-0.28)/0.02 which equals 36 pg of THC (you subtract the THC-COOH that has 100% cross reactivity and assume the remaining signal comes from THC). However, the initial extraction process used by Omega is likely poor and decontamination is nonexistence so it is difficult to compare the initial test to the more careful confirmation result as to just what the ELISA is responding is unknown. Nevertheless, either method shows that THC is much greater than THC-COOH in this hair sample.
[71] This is obvious from page 7 of the Omega report. All the other drugs have the same screening and confirmation cut-offs. THC is 10 fold lower in the confirmation than the screening test.
[72] According to the experience of Dr. James Bourland (the laboratory director of Associated Pathologist Laboratory which was purchased by Quest Diagnostics): "The 1 pg/mg does refer to the carboxy metabolite, which is used as the standard. Based on the pre-analytical process used, at least in our hands and my experience, THCA is not being extracted. THC parent is extracted which then cross-reacts enough with that antibody to produce a reaction. THC parent is from 50 -100 times more concentrated than the metabolite in hair. Whether you call it carboxy or THC, the THC provides the response." From July 2013 DTAB transcript.
[73] D.A. Kidwell and F.P. Smith, "Companies should test the limits of their decontamination procedures—Reply to: Comments on ''Ethnic hair care products may increase false positive in hair'' V. Hill et al.", *Forensic Science International*, **259** (2016) e48-e50.
[74] The written documents states vortex mix for five seconds (p. 58). However, Ms. Vinsick (LV 82:3) testimony was that the wash was five minutes. It is possible that the written documentation really means – vortex mix 5 seconds and let stand for 5 mins. That would make more sense from a scientific standpoint.
[75] Having too much internal standard does NOT generate a false positive from Officer Kennedy's sample. In fact, it actually makes it more negative than it would be normally. I bring up the subject to indicate that something is wrong with the analysis in this whole batch of samples. In the notes (Omega p. 59), they reran a number of samples because the negative controls failed. No mention was made of why the controls failed but it is safe to assume that the negative control failed due to cross contamination *i.e.* they were not negative when they should be. Omega did not rerun Officer Kennedy's sample and the negative control appears to pass their criteria. However, this negative control was run some four samples before Officer Kennedy's sample. If they were having carry-over problems (as indicated by the negative controls failing), it would have been wise to rerun all positive samples with blanks in between. Carry-over could occur at any point in the analysis – and more likely during the extraction. Re-preparing samples should be done from the start of the extraction process with new hair samples. Of course, this is a lot of work but necessary for good forensic analysis. After all, frequently the only indication illicit substance use is the laboratory report. Therefore, it must be scientifically sound. If there was insufficient sample to repeat the analysis, then it should be reported as negative.
[76] Generally, you take the ratio of sample to internal standard and divide by the slope. Depending on your biases, you can force the line though zero or use the intercept in the calculation. I like to use the intercept if it is positive, but force the line though zero if a standard least squares analysis produces a negative intercept. In that manner, you are biasing the results to the negative (i.e. under estimating the amount of analyte present). Scientifically, the meaning of a negative intercept is not clear – you cannot have a negative amount of something. Omega uses the intercept and in this case, it is negative. Preforming the calculation in that manner inflates the result by about 5%. In the present case, this would not make a difference in determining if the sample were positive or negative.
[77] Although technically one could synthesize pentafluoroacetic anhydride, it would be very difficult. Additionally, using that reagent would not produce the mass spectrums in the litigation package (the

masses of the parent ion (actually a fragment of loss of HF (20) from the molecule) would be a mixture of ions some 50 and 68 mass units lower than observed).

[78] The laboratory documentation contains an error. It should say PFPA.

[79] https://www.usdtl.com/collection/procedures

[80] Product literature from USDTL just indicates that they decontaminate the hair BEFORE the initial testing with an organic solvent. However, published reports from their laboratory indicate that they use methylene chloride for 10 mins. Methylene chloride is especially efficacious for oil removal. See: Christine Moore and Frank Guzaldo, "The Determination of 11-nor-Ag-Tetrahydrocannabinol- 9-Carboxylic Acid (THC-COOH)in Hair using Negative Ion Gas Chromatography-Mass Spectrometry and High-Volume Injection", *Journal of Analytical Toxicology*, **25** (2001) 555.

[81] In my preliminary look at this case, I requested what hair care products Officer Kennedy had used. I was sent pictures of the two hair care products in question and the full names are: Wild Growth Light Oil Moisturizer® and Jamaican Mango & Lime™ Cactus Oil. From an internet search of their ingredients (i.e. the actual bottles were not tested), there is no indication that either product had materials derived from marijuana and thus are unlikely to be the source of THC-COOH in Officer Kennedy's hair.

[82] Doing a direct comparison of urine and hair testing is difficult. One example in planned testing is in Germany for Driver license renewal. If an individual is found DWUI, they lose their license and must prove that they are drug-free for a year to regain it. Germany uses hair and urine testing for that assessment at basically as low of levels of testing as possible. They are random tests with a 24 hr window to report. See: Ronald Agius and Thomas Nadulski, "Utility of ELISA screening for the monitoring of abstinence from illegal and legal drugs in hair and urine", (www.drugtestinganalysis.com) DOI 10.1002/dta.1644. From this paper, they calculate a sensitivity of 95% for hair and 87% for urine in this population. No mention is made if the urine samples are physiologically diluted as the subjects had 24 hr to prepare for the test. However, all the urine levels were very low. These were not matched pairs and the actual positive rates were very low.

[83] The City did provide names of offices who had hair drug tests performed. As mentioned before, all of these were via urinalysis with 10% via hair testing. There was not a breakout of those that had hair testing done. Therefore, the number of hair tests passed by the urine-positive officers could not be determined.

[84] According to the testimony of Bonney Trent, the LabCorp representative, they use a cut-off of 50 ng/mL for THC-COOH in urine. Whereas the City through Drug Scan uses 20 ng/mL.

[85] Cynthia L. Morris-Kukoski, Madeline A. Montgomery, and Rena L. Hammer, "Analysis of Extensively Washed Hair from Cocaine Users and Drug Chemists to Establish New Reporting Criteria", *Journal of Analytical Toxicology*, **38** (2014) 628–636.

[86] A staged urinalysis program would be used - more frequent initially and less as time progressed.

[87] A policy decision could be implemented to fire individuals placed in a urinalysis program due to a positive hair test and thereby denying them some earned benefits. Alternatively, they could refuse such a program, resign or retire, and take what earned benefits with them at that time. The financial incentives and possible black mark of being fired would be an incentive for the addicted individual to quite rather than actually be fired. Cost of even weekly urine tests are dwarfed by the costs of training a replacement officer. A urinalysis program has never been shown to be racially biased, whereas hair testing has been in at least one court case (see: Hon. G.A. O'Toole, Jr., U.S. District Judge, United States Court of Appeals for the First Circuit, No. 12-2280, Ronnie Jones, et al. vs. City of Boston, Boston Police Department; Edward Davis, Commissioner of the Boston Police Department, Appeal From the United States District Court for the District of Massachusetts, 05/07/2014).